Point-of-care CYP2C19 genotyping in patients prescribed clopidogrel therapy following a percutaneous coronary intervention

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Background

The Spartan RX CYP2C19 assay (Spartan Bioscience, Canada) is a point-of-care (POC), rapid, automated, non-invasive test, capable of identifying carriers of the CYP2C19 loss-of-function (LoF) *2 allele from genomic DNA obtained from a buccal sample. To-date, limited data exists regarding the use of POC CYP2C19 testing.[1,2]

Objective

To implement a POC, pharmacist-led process to identify presence of the CYP2C19 LoF *2 allele in patients who were prescribed clopidogrel therapy post-percutaneous coronary intervention (PCI), using the Spartan RX CYP2C19 system.

Methods

- University Research Ethics Committee approval was granted.
- Inclusion criteria for patient recruitment were: Age ≤ 75 years, body weight > 60 kg, no history of stroke or transient ischaemic attack and prescribed clopidogrel therapy post-PCI.
- Training on the Spartan RX CYP2C19 system was undertaken and patients were recruited over a 3-month period (October to December 2014). One test was used as an external positive control.
- After obtaining informed written consent, each patient was requested to rinse the oral cavity with water and a buccal sample was acquired.
- The swab was transported to the analyser in temperature-controlled conditions, air bubbles were removed, and the sample was put into the analyser for automated genotype analysis.
- A printed result was obtained after 60 minutes. One of 3 genotype results was possible: Not a carrier of the *2 allele, carrier of one *2 allele, or carrier of two *2 alleles. Test failures and inconclusive tests should be repeated with a new test.

Setting

Cardiac Catheterisation Suite, Cardiology Department, Mater Dei Hospital

Results

First-run genotype results

Out of the 39 available tests, 30 first-run genotype results (76.9%) were obtained. In 4 tests a failure resulted; these 4 tests were repeated and a genotype result was obtained on the second-run. One test was inconclusive and was not repeated since the patient was already discharged home. The total sample consisted of 34 patients.

Patient baseline characteristics (N=34)

Age (mean 66 years; range 49-75 years), gender (25 male, 9 female), ethnicity (all Caucasian), previous PCI (12), clinical presentation of myocardial infarction (16)

CYP2C19 genotype analysis

Thirteen patients were carriers of the CYP2C19 LoF *2 allele (Table 1).

Table 1: CYP2C19 genotype distribution

CYP2C19 genotype	Number (%) of patients
Non-carrier of *2 allele	21 (61.8)
Carrier of one *2 allele	12 (35.3)
Carrier of two *2 alleles	1 (2.9)

Cost of tests

The estimated direct cost per test is € 225.00.

Conclusions

This POC system is user-friendly and provides a quick result to identify patients who are carriers of the CYP2C19 LoF *2 allele. According to the Clinical Pharmacogenetics Implementation Consortium guidelines[3], carriers of one or two *2 alleles (38%) should be switched to an alternative antiplatelet agent, unless contra-indicated. A failure rate for successful first-time genotype result of 12.8% was obtained and needs to be incorporated into the pharmacoeconomic model for the evaluation of this service.

References

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Acknowledgements

This research was carried out in collaboration with all the consultant cardiologists, doctors, nurses and staff at the Cardiology Department, MDH. This research was funded by Technoline Ltd. and supported by the University of Malta Faculty of Medicine and Surgery Dean's Initiative and Orme Scientific Ltd.